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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,270	11/24/1999	DAVID HARTLEY	PA-5169-CON	6069
9896 7590 02/29/2008 COOK GROUP PATENT OFFICE P.O. BOX 2269 BLOOMINGTON, IN 47402				
EXAMINER WOO, JULIAN W				
ART UNIT 3773		PAPER NUMBER		
MAIL DATE 02/29/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/449,270

Applicant(s)

HARTLEY ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 18-31, 33 and 36-42 is/are rejected.
- 7) ☒ Claim(s) 32, 34 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25-31, 37, 38, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 25, "the proximal attachment means" lacks antecedent basis. With respect to base claim 37, "the thick walled tube" lacks antecedent basis. With respect to claim 40, "the external sheath" lacks antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-11, 18-27, 29, 30, 33, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Campbell et al. (6,139,572). With respect to claims 1-11 and 18-23, Campbell et al. disclose, at least in figures 2 and 8-11 and in col. 5, line 62 to col. 6, line 52; an introducer or endovascular arrangement including a prosthesis positioning mechanism (19), a first control member (81) separable from a prosthesis, a second

control member (15), and a distal attachment region (at 17) with a distal attachment device (39) and a proximal attachment region (at 22) with a proximal attachment device (22), where the prosthesis positioning mechanism includes a control arrangement or a rotational arrangement (83 and 13) that can adjust the relative angular orientation of the proximal and distal portion of the prosthesis or adjust the angular orientation of the prosthesis, where the introducer or arrangement includes an expansion control mechanism (85, 24, and/or 21); where the endovascular arrangement includes a control section (at 20), a first member (83), a second member (13), and a contraction means (17) with a tubular means (39); where the second member has means for controlling the distal end of the stent (15), where the arrangement includes release mechanisms in the control section (85, 21) for controlling wires extending to stents (i.e., the wires forming the stents) of the prosthesis. With respect to claims 24-27, 29, 30, 33, and 40, Campbell et al. disclose an introducer including a proximal attachment device (81), a distal attachment device (15) with a streamlined shape, and proximal releasing means (22) and distal releasing means (17); where the proximal attachment means has a long flexible extension on its proximal end (proximal portion of 11), where the proximal attachment device is mounted on a flexible thin walled tube (83), where the flexible thin walled tube includes fluid connection means (24), where the distal attachment device is mounted on a flexible thick walled tubing (13), where the introducer includes a hemostatic seal between the thin walled tube and the thick walled tube (at the junction proximal of 83), where the introducer includes a distal trigger wire (19), and where the

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distal attachment device is adapted to be advanced to the proximal attachment device to allow smooth retrieval through a released prosthesis and into an external sheath (83).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (6,139,572) in view of St. Germain et al. (5,534,007). Campbell et al. disclose the invention substantially as claimed, but do not disclose a longitudinally movable external sheath to cover and compress the prosthesis, where the sheath has a tapered and smooth proximal end, and where the external sheath is adapted to have a tight fit onto a proximal attachment device. St. Germain et al. teach, at least in figures 1-5, an introducer including a longitudinally movable external sheath (40 or 75) to cover and compress a prosthesis (35), where the sheath has a tapered and smooth proximal end (at 80 as seen in fig. 4), and where the external sheath is adapted to have a tight fit

onto a proximal attachment device (60). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of St. Germain et al., to include an external sheath as claimed with the device of Campbell et al., so that the device of Campbell et al. can be used with a self-expandable stent. Such a sheath would allow constraint and protection of the self-expandable stent during movement of the introducer through a vessel, and it would allow the release and positioning of the self-expandable stent (without the need for inflated balloons) at a desired location in the vessel.

7. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (6,139,572) in view of Goicochea et al. (5,609,627). Campbell et al. disclose the invention substantially as claimed, but do not disclose that the prosthesis is bifurcated and is adapted to repair an aortic aneurysm and that the introducer is applied in an aorta. Goicochea et al. teach, at least in figures 11-16 and in col. 14, line 53 to col. 15, line 47; an introducer (100) and a bifurcated prosthesis (12) applied in an aorta and an aortic aneurysm. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Goicochea, to apply the introducer of Campbell et al. with a bifurcated prosthesis in an aortic aneurysm. Such an application and such a prosthesis would allow the treatment of an aortic aneurysm without requiring bypass surgery.

Allowable Subject Matter

8. Claims 28 and 31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
9. Claims 32, 34, and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an introducer includes, inter alia, proximal and distal attachment devices and proximal and distal releasing means, where the proximal attachment device includes a long flexible extension with a hollow tube having a plurality of side holes to enable dispersion of a medical reagent proximal of the prosthesis, where the introducer includes means for introducing a medical reagent into an annular space between thin-walled and thick-walled tubes, where the introducer includes a proximal trigger wire extending from the proximal attachment device to the manipulation section and adapted to activate the proximal releasing means, and where the introducer includes an external release mechanism for each of proximal and distal trigger wires.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

11. Applicant's arguments with respect to claims 1-11, 18-31, 33, and 36-42 have been considered but are moot in view of the new ground(s) of rejection. The indication of the allowability of claims 24-42 is hereby withdrawn.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Baker et al. (5,693,083) and Euteneuer et al. (6,562,063) teach introducers.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/

Primary Examiner, Art Unit 3773

March 1, 2008